

Serial No. 10/777,771

Page - 2 -

AMENDMENTS TO THE CLAIMS

1-6 (Cancelled).

7 (Previously Presented). A neuromuscular stimulation assembly comprising at least one electrode sized and configured for implantation in a targeted neural or muscular tissue region,

a percutaneous lead electrically coupled to the electrode and including an exposed region adapted to be projecting through an external skin surface,

a carrier sized and configured to be worn on the external skin surface,

circuitry carried on-board the carrier configured to generate a stimulation pulse,

a communication bay carried on-board the carrier that is electrically coupled to the circuitry, the communication bay being sized and configured to establish a communication link between the circuitry and an external device, the communication bay also being sized and configured to hold a power source, and

an electrode connection element carried on-board the carrier that is electrically coupled to the circuitry, the electrode connection element being sized and configured to electrically engage at least a portion of the exposed region of the lead to electrically couple the electrode to the circuitry to percutaneously apply the stimulation pulse to the tissue region.

8 (Previously Presented). A neuromuscular stimulation assembly comprising at least one electrode sized and configured for implantation in a targeted neural or muscular tissue region,

a percutaneous lead electrically coupled to the electrode and including an exposed region adapted to be projecting through an external skin surface,

a carrier sized and configured to be worn on the external skin surface,

circuitry carried on-board the carrier configured to generate a stimulation pulse,

a communication bay carried on-board the carrier that is electrically coupled to the circuitry, the communication bay being sized and configured to establish a communication link between the circuitry and an external device, the communication bay also being sized and configured to hold a power source that can be released and replaced, and

an electrode connection element carried on-board the carrier that is electrically coupled to the circuitry, the electrode connection element being sized and configured to electrically

Serial No. 10/777,771

Page - 3 -

engage at least a portion of the exposed region of the lead to electrically couple the electrode to the circuitry to percutaneously apply the stimulation pulse to the tissue region.

9 (Original). An assembly according to claim 8

further including instructions prescribing the release and replacement of the power source according to a preset schedule.

10 (Original). An assembly according to claim 7 or 8

wherein the power source comprises a battery.

11-12 (Cancelled).

13 (Previously Presented). A neuromuscular stimulation assembly comprising

at least one electrode sized and configured for implantation in a targeted neural or muscular tissue region,

a percutaneous lead electrically coupled to the electrode and including an exposed region adapted to be projecting through an external skin surface,

a carrier sized and configured to be worn on the external skin surface,

circuitry carried on-board the carrier configured to generate a stimulation pulse, the circuitry including programmable code that governs generation of the stimulation pulse,

a communication bay carried on-board the carrier that is electrically coupled to the circuitry, the communication bay being sized and configured to establish a communication link between the circuitry and an external device to program the programmable code, the communication bay also being sized and configured to hold a power source, and

an electrode connection element carried on-board the carrier that is electrically coupled to the circuitry, the electrode connection element being sized and configured to electrically engage at least a portion of the exposed region of the lead to electrically couple the electrode to the circuitry to percutaneously apply the stimulation pulse to the tissue region.

14 (Previously Presented). An assembly according to claim 13

wherein the communication bay is also sized and configured to hold a power source that can be released and replaced.

15 (Original). An assembly according to claim 14

further including instructions prescribing the release and replacement of the power source according to a preset schedule.

16 (Original). An assembly according to claim 13 or 14

Serial No. 10/777,771

Page - 4 -

wherein the power source comprises a battery.

17 (Cancelled).

18 (Previously Presented). A neuromuscular stimulation assembly comprising at least one electrode sized and configured for implantation in a targeted neural or muscular tissue region,

a percutaneous lead electrically coupled to the electrode and including an exposed region adapted to be projecting through an external skin surface,

a carrier sized and configured to be worn on the external skin surface,

circuitry carried on-board the carrier configured to generate a stimulation pulse,

an electronics bay carried on-board the carrier that is sized and configured to hold the circuitry for selective release from the carrier, and

an electrode connection element carried on-board the carrier that is electrically coupled to the circuitry, the electrode connection element being sized and configured to electrically engage at least a portion of the exposed region of the lead to electrically couple the electrode to the circuitry to percutaneously apply the stimulation pulse to the tissue region.

19 (Previously Presented). A neuromuscular stimulation assembly comprising

at least one electrode sized and configured for implantation in a targeted neural or muscular tissue region,

a percutaneous lead electrically coupled to the electrode and including an exposed region adapted to be projecting through an external skin surface,

a carrier sized and configured to be worn on the external skin surface,

a region carried on-board the carrier sized and configured to adhere the carrier to the external skin surface and to accommodate selective detachment of the carrier from the external skin surface,

circuitry carried on-board the carrier configured to generate a stimulation pulse, and

an electrode connection element carried on-board the carrier that is electrically coupled to the circuitry, the electrode connection element being sized and configured to electrically engage at least a portion of the exposed region of the lead to electrically couple the electrode to the circuitry to percutaneously apply the stimulation pulse to the tissue region.

20 (Previously Presented). A neuromuscular stimulation assembly comprising

Serial No. 10/777,771

Page - 5 -

at least one electrode sized and configured for implantation in a targeted neural or muscular tissue region,

a percutaneous lead electrically coupled to the electrode and including an exposed region adapted to be projecting through an external skin surface,

a carrier sized and configured to be worn on the external skin surface, the carrier comprises separable sections that can be manipulated to open the carrier to accommodate passage of the exposed region of the lead into electrical engagement with an electrode connection element and to close the carrier to capture the exposed region of the lead within the electrode connection element,

circuitry carried on-board the carrier configured to generate a stimulation pulse, and the electrode connection element being carried on-board the carrier and electrically coupled to the circuitry, the electrode connection element being sized and configured to electrically engage at least a portion of the exposed region of the lead to electrically couple the electrode to the circuitry to percutaneously apply the stimulation pulse to the tissue region.

21 (Previously Presented). A neuromuscular stimulation assembly comprising

at least one electrode sized and configured for implantation in a targeted neural or muscular tissue region,

a percutaneous lead electrically coupled to the electrode and including an exposed region adapted to be projecting through an external skin surface,

a carrier sized and configured to be worn on the external skin surface,

circuitry carried on-board the carrier configured to generate a stimulation pulse, and

an electrode connection element carried on-board the carrier that is electrically coupled to the circuitry, the electrode connection element comprises a trough to route the exposed region of the lead, the electrode connection element being sized and configured to electrically engage at least a portion of the exposed region of the lead to electrically couple the electrode to the circuitry to percutaneously apply the stimulation pulse to the tissue region.

22 (Currently Amended). A neuromuscular stimulation system comprising

a carrier sized and configured to be worn on an external skin surface at or near a targeted neural or muscular region, the carrier including circuitry configured to generate a stimulation pulse, a power input bay sized and configured to hold a disposable battery for the circuitry that can be released and replaced for powering ~~recharging~~ the circuitry, and an electrode

Serial No. 10/777,771

Page - 6 -

connection element that is sized and configured to electrically engage an electrode lead for an electrode that has been percutaneously implanted in the targeted tissue region, to percutaneously apply the stimulation pulse to the targeted tissue region,

instructions furnished by a clinician or caregiver or physician prescribing the release and replacement of the disposable battery according to a prescribed battery replacement regime, the prescribed battery replacement regime comprising the replacement of the disposable battery on a prescribed repeated basis similar to administering a pill under a prescribed pill-based medication regime preset schedule, and

a supply of disposable batteries, each battery comprising a dose of power for the circuitry for administration according to the prescribed battery replacement regime, for recharging the circuitry according to the preset schedule.

23 (Original). A system according to claim 22

wherein the circuitry includes programmable code governing generation of the stimulation pulse.

24 (Original). A system according to claim 23

wherein the carrier includes means for establishing a communication link between the circuitry and an external device to program the programmable code.

25 (Currently Amended). A method for providing a neuromuscular stimulation function comprising

providing a neuromuscular stimulation system comprising a carrier sized and configured to be worn by an individual, the carrier including circuitry configured to generate a stimulation pulse, a power input bay sized and configured to hold a disposable battery for the circuitry that can be released and replaced for powering ~~recharging~~ the circuitry, and an electrode connection element that is sized and configured to electrically engage an electrode lead for an electrode that has been percutaneously implanted in a targeted tissue region, to percutaneously apply the stimulation pulse to the targeted tissue region,

providing instructions furnished by a clinician or caregiver or physician prescribing the release and replacement of the disposable battery according to a prescribed battery replacement regime, the prescribed battery replacement regime comprising the replacement of the disposable battery on a prescribed repeated basis similar to administering a pill under a prescribed pill-based medication regime preset schedule, and

Serial No. 10/777,771

Page - 7 -

providing a supply of disposable batteries, each battery comprising a dose of power for the circuitry for administration according to the prescribed battery replacement regime, for recharging the circuitry according to the preset schedule.

26. (Original). A method according to claim 25 wherein the neuromuscular stimulation function includes a function selected from a group comprising (i) maintenance of muscle function; (ii) tissue or bone regeneration; (iii) continuous active motion therapy; (iv) anti-scarring treatment; (v) diagnostic assessment; (vi) neuroplasticity therapy; (vii) anti spasm therapy; (viii) pain therapy; (ix) post-surgical reconditioning; (x) anti-thrombosis therapy; and (xi) treatment of osteoporosis.

27 (Withdrawn). A percutaneous electrode assembly comprising
a flexible body including an electrically conductive region, a tissue penetrating region for implantation of the electrically conductive region in a targeted tissue region, and a percutaneous lead electrically coupled to the electrically conductive region,

an anchoring element on the flexible body to resist movement of the electrically conductive region within tissue, and

an introducer having an interior lumen sized and configured to receive the flexible body and shield the anchoring element from contact with tissue while the electrically conductive region is placed to a desired position within tissue, the introducer also being sized and configured to accommodate advancement of the anchoring element beyond the interior lumen for contact with tissue to resist movement of the electrically conductive region placed in the desired position.

28 (Withdrawn). A method of implanting a percutaneous electrode comprising the steps of

providing a percutaneous electrode with an anchoring element to resist movement of the percutaneous electrode within tissue,

inserting the percutaneous electrode within an introducer that shields the anchoring element from contact with tissue,

implanting the percutaneous electrode while inserted within the introducer, to place the percutaneous electrode in a desired location within tissue, and

withdrawing the introducer to place the anchoring element in contact with tissue, thereby resisting movement of the percutaneous electrode from the desired position.

29 (Withdrawn). A method according to claim 28

Serial No. 10/777,771

Page - 8 -

further including, during the implanting step, a step of coupling the percutaneous electrode to a stimulating circuit to provoke a tissue stimulation response to place the percutaneous electrode in the desired location.

30 (Previously Presented). An assembly according to claim 20

wherein the electrode connection element comprises a trough to route the exposed region of the lead.

31 (Currently Amended). A neuromuscular stimulation system comprising

a carrier sized and configured to be worn by an individual, the carrier including circuitry configured to generate a stimulation pulse, a power input bay sized and configured to hold a disposable battery for the circuitry that can be released and replaced for ~~powering~~ recharging the circuitry, and an electrode connection element that is sized and configured to electrically engage an electrode lead for an electrode that has been percutaneously implanted in a targeted tissue region, to percutaneously apply the stimulation pulse to the targeted tissue region,

instructions furnished by a clinician or caregiver or physician prescribing the release and replacement of the disposable battery according to a prescribed battery replacement regime, the prescribed battery replacement regime comprising the replacement of the disposable battery on a prescribed repeated basis similar to administering a pill under a prescribed pill-based medication regime preset schedule, and

a supply of disposable batteries, each battery comprising a dose of power for the circuitry for administration according to the prescribed battery replacement regime, for recharging the circuitry according to the preset schedule.

32 (Previously Presented). A system according to claim 31

wherein the circuitry includes programmable code governing generation of the stimulation pulse.

33 (Previously Presented). A system according to claim 32

wherein the carrier includes means for establishing a communication link between the circuitry and an external device to program the programmable code.

34 (New). A system according to claim 22 or 31

wherein the prescribed battery replacement regime comprises the replacement of the disposable battery repeated at least on about a daily basis.

35 (New). A system according to claim 22 or 31.

Serial No. 10/777,771

Page - 9 -

wherein the prescribed battery replacement regime comprises the replacement of the disposable battery repeated at least on about a weekly basis.

36 (New). A method according to claim 25

wherein the prescribed battery replacement regime comprises the replacement of the disposable battery repeated at least on about a daily basis.

37 (New). A method according to claim 25

wherein the prescribed battery replacement regime comprises the replacement of the disposable battery repeated at least on about a weekly basis.